K033580

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AUG - 5 2004

NexFlex™ Total Hip System
510(k) SUMMARY
November 2003

I. **Company**: Nexmed, Inc.
6110 Corte Del Cedro
Carlsbad, CA 92009
USA
(760) 431-9286

II. **Contact Person**: Ellen Yarnall, Director of Regulatory Affairs

III. **Trade/Proprietary Name**: NexFlex™ Total Hip System with HA Coating

IV. **Product Description**:

The NexFlex™ Total Hip System is a sterile total or hemi-hip replacement system. It consists of a series of femoral and acetabular implants that are used to help restore patient range of motion and aid in the treatment of other deformities as listed in the *Indications for Use*.

The purpose of this 510(k) is to provide for HA coated hip stems and acetabular cups. This submission also includes additions / modifications to the system cleared under formal change control procedures.

V. **Indications for Use:**

1) When used as a hemi-hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

2) When used as a total hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

3) In addition, the NexFlex Total Hip System is intended for cases where alternative modes of treatment appear less preferable and the associated risks of a total hip replacement are thought to be acceptable. It is intended for severely disabled joints, which could result from arthritis or late stages of avascular necrosis and revisions of unsuccessful acetabular cup arthroplasty and/or femoral procedure.

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VI. Substantial Equivalence:

The NexFlex Total Hip System with HA coated components is substantially equivalent to various total hip and hemi-hip systems commercially available.

VII. Performance Data:

Fatigue testing and microstructure examination the NexFlex Total Hip System was previously submitted. The test results demonstrated that the mechanical performance and biocompatibility characteristics are at least comparable to, if not better than, those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2004

Ms. Ellen A. Yarnall
Director of Regulatory Affairs
Nexmed, Inc.
6110 Corte Del Cedro
Carlsbad, California 92009

Re: K033580
Trade/Device Name: Nexflex Total Hip System
Regulation Number: 21 CFR 888.3358; 21 CFR 888.3350; 21 CFR 888.3390
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI, KWY
Dated: July 5, 2004
Received: July 7, 2004

Dear Ms. Yarnall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

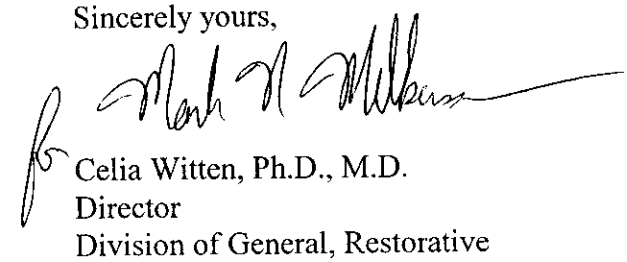
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033580

Device Name: NexFlex™ Total Hip System

Indications for Use:

1) When used as a hemi-hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

2) When used as a total hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

3) In addition, the NexFlex Total Hip System is intended for cases where alternative modes of treatment appear less preferable and the associated risks of a total hip replacement are thought to be acceptable. It is intended for severely disabled joints, which could result from arthritis or late stages of avascular necrosis and revisions of unsuccessful acetabular cup arthroplasty and/or femoral procedure.

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033580

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use ____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)